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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1646	

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21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/612,921	SIMS, JOHN E.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 19, 2003 has been entered.

Response to Amendment

2. Claims s 1-57 have been cancelled and claims 58-78 have been added as requested in the amendment of Paper No. 20, filed on May 19, 2003. Claims 58-78 are pending in the instant application.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on May 19, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Sequence compliance

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2).

However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence listing has been provided which includes the sequences presented on page 59, lines 28-29 and 60, lines 13-14 of the instant specification. In case these sequences are new, Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

Applicant is advised to review the entire text of the instant specification for other unidentified sequences.

Specification

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 53, lines 20-23, for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Applicant is advised to review the entire text of the instant specification for other possible use of embedded hyperlinks.

Claim Objections

8. Claim 64 is objected to because of the following informalities: "hybridizes either strand" should be "hybridizes to either strand", perhaps. Appropriate correction is required.

Claim Rejections - 35 USC § 101

9. Claims 58-78 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record as applied to claims 13-15, 22-24 and 35 in section 3 of Paper No. 8, section 5 of Paper No. 12 and section 5 of Paper No. 17. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Applicant submits that the instant "specification asserts a specific utility for those nucleic acids, namely, that all or a portion of the nucleic acids of SEQ ID NO: 3, including oligonucleotides, can be used by those skilled in the art in well-known techniques to identify human chromosome 2, to analyze abnormalities associated with gene mapping to chromosome 2, to distinguish conditions in which marker is rearranged or deleted, and as a positional marker to

map other genes of unknown location" (page 6, last paragraph of the Response). This argument has been fully considered but is not deemed persuasive for the following reasons.

As it was fully explained in the previous office action (see section 5 of Paper No. 17), the employment of DNA sequences of the instant invention as a chromosome marker is not a substantial or specific utility. One skilled in the art readily understands that DNA encoding IL-1 delta is not the only DNA that can be used to specifically identify chromosome 2. Therefore, to accept Applicant's arguments that a nucleic acid encoding a protein of human origin is useful as a chromosome marker would be comparable to conceding that any object of fixed mass has *prima facie* utility as a weight standard, irrespective of any other properties possessed by that object.

The Examiner maintains the position because the biological function of the claimed nucleic acids encoding human IL-1 delta polypeptides is not established in the instant specification, as filed, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful. Applicant's attention is directed to Example 12 of the "Revised interim utility guidelines training materials", which explains why an isolated nucleic acid encoding an "orphan receptor" lacks utility in the absence of the disclosure of a specific role for either the nucleic acid or protein in a known disease or disorders or a physiological process which one would wish to manipulate for clinical effect.

To grant Applicant a patent encompassing an isolated polynucleotide encoding a naturally occurring human protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and

"confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed polynucleotide based solely upon an assertion that the protein encoded thereby can be employed as a chromosome marker is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted and would be no different than granting a patent on the process disputed in *Brenner v. Manson* on the premise that the steroid produced thereby was useful as an analytical standard or as a fuel source.

Applicant further supports the arguments regarding asserted utility of IL-1 delta as a chromosome marker by referring to the scientific publications regarding analysis of chromosomal rearrangements within different pathological conditions (pages 8-11 of the Response). However, it appears that none of the quoted references were presented with the Response and, therefore, could not been considered. Applicant is advised that references filed as a part of the Response could be only considered in so far as they have been relied upon to support Applicant's arguments. If Applicant wishes these references to be considered in their entirety, Applicant needs to submit the references in a form of proper IDS in accordance with 37 CFR § 1.97.

Applicant's arguments that IL-1 delta polypeptides could be useful in binding assays to identify IL-1 delta receptors (page 13 of the Response), and further, "in the detection and removal of cross-reacting antibodies in preparation of polyclonal antisera against IL-1ra" (page 14, second paragraph) have been fully considered but are not deemed persuasive for the reasons fully explained earlier in the instant office action as well as in section 5 of Paper No. 17. Briefly, to employ the instant IL-1 delta to identify IL-1 delta receptors is not specific substantial and

credible utility because it would eventually relate to a protein for which no biological function is known. To employ a nucleic acid of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the encoded protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

10. Claims 58-78 are rejected under 35 U.S.C. 112, first paragraph for reasons of record as applied to claims 42-57 in section 6 of Paper No. 17. Briefly, because the instant specification does not disclose specific, substantial and credible utility of the claimed isolated nucleic acids, then one skilled in the art clearly would not know how to use the claimed invention.

11. Claims 64-71 and 73-78 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the full length of an isolated nucleic acid molecule of SEQ ID NO: 3, does not reasonably provide enablement for any nucleic acid encoding a fragment of SEQ ID NO: 4, such fragment that has an ability to bind to cells expressing an IL-1 delta receptor for reasons of record as originally submitted in sections 4 of Paper No. 8 and section 5b of Paper No. 12 and also reasons of record as applied to claims 42-55 in section 7 of Paper No. 17.

Applicant submits that "[t]he fact that some screening, even a very large amount of screening, is required cannot serve as the basis for concluding that undue experimentation is required " (page 17, second paragraph of the Response). The Examiner maintains the position

that without identification of specific residues that are critical for binding to an IL-1 delta receptor, one skilled in the art would be left with no guidance or working examples to determine, which fragment, if any, of SEQ ID NO: 3 would encode a fragment of unknown structure or length, a fragment that will bind to IL-1 delta receptor. Therefore, one would reasonably conclude that such experimentation, as to practicing if any fragment of 468 nucleic basis of SEQ ID NO: 3 would encode a fragment that will bind to IL-1 delta receptor, is undue. Finally, the instant specification fails to provide any evidence or sound scientific reasoning that a polypeptide encoded by the nucleic of claims 71 and 78, section (c) wherein all Cys residues are deleted or substituted, which would lead to a complete alteration in protein structure, would have the ability to bind to IL-1 delta receptor.

12. Claims 60-61, 64-71, 73-78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See reasons of record in section 4d of Paper No. 8 and on pages 10-11 of Paper No.12, and especially reasons of record as applied to claims 42-55 in section 8 of Paper No. 17.

Applicant submits that the instant specification provided the complete sequences of IL-1 delta, as well as teachings that "selected C-terminal amino acids may be deleted, and [...] selected N-terminal amino acids may be deleted [...]. Based on this information, the skilled artisan would be able to envision numerous additional IL-delta variants" (page 18, last paragraph going to page 19, first paragraph of the Response). These arguments have been fully considered but are not deemed persuasive for the reasons that follow.

The instant specification, as filed, describes only a nucleic acid of SEQ ID NO: 3 and encoded protein having the amino acid sequence of SEQ ID NO:4. The specification fails to teach or describe any other nucleic acid which lacks the nucleic acid of SEQ ID NO: 3 and encodes a protein that has the activities possessed by the IL-1 delta polypeptide. Therefore, the instant specification fails to describe the entire genus of nucleic acids, which are encompassed by these claims and, consequently, there is a lack of guidance regarding structure and function of the claimed sequences because there is only a single example provided in the specification and because there is no guidance found in the prior art. Furthermore, the instant application fails to recite relevant identifying characteristics, such as physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure, sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize that Applicant was in possession of the claimed invention.

13. Claims 63-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention for those reasons of record as applied to claims 52-55 in section 9 of Paper No. 17.

Claims 63 and 64 are directed to a nucleic acid that hybridizes to either strand of SEQ ID NO: 3 and encodes a polypeptide of SEQ ID NO: 4 or a polypeptide that binds to cells expressing an IL-1 delta receptor. Claims 65-71 are dependent claims. There is no existing knowledge in the art and there is no guidance in the instant specification to teach a skilled artisan how to make a nucleic acid that encodes a specific polypeptide from an antisense strand. It

would require undue experimentation on part of one skilled in the art to discover how to practice the instant invention as currently claimed.

Applicant's argument that "the antisense DNA molecule and sense RNA molecule encode the polypeptide" (page 20, second paragraph of the Response) contradicts fundamental knowledge in modern biology. Complementary sequences do not encode the same protein that is encoded by the coding strand of DNA. This is why the complementary strand of a DNA encoding a protein is referred to as the antisense strand. If Applicant is aware of any art, which demonstrates the opposite point of view, then Applicant is strongly encouraged to make such art of record.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 58 and 70-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claim 58 is vague and indefinite for recitation "consisting essentially of". The metes and bounds of the recitation cannot be determined form the claim or the instant specification. Specifically, an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

16. Claims 70-71 are vague and ambiguous because it is not clear what polypeptide is intended by the claims. Claims 70-71 depend from claim 64, which is not limited to a nucleic acid encoding a polypeptide. Clarification is required.

Double Patenting

17. Applicant is advised that should claim 58 be found allowable, claim 59 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

MPEP 2111.03 states that "For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355". Therefore, claims 58 and 59 are claiming the same subject matter. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

18. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
June 25, 2003